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INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)


13 APR 2005

Applicant's or agent's file reference ESNZ 2 00028	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/US 03/33240	International filing date (day/month/year) 22.10.2003	Priority date (day/month/year) 23.10.2002
International Patent Classification (IPC) or both national classification and IPC A61G7/057		
Applicant TCAM TECHNOLOGIES, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 22.04.2004	Date of completion of this report 16.03.2005
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Amghar, N Telephone No. +31 70 340-3909



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US 03/33240

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*):

Description, Pages

1, 2, 5-12 as originally filed
3, 4 received on 08.11.2004 with letter of 08.11.2004

Claims, Numbers

1-23 received on 08.11.2004 with letter of 08.11.2004

Drawings, Sheets

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-23
	No: Claims	
Inventive step (IS)	Yes: Claims	1-23
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-23
	No: Claims	

2. Citations and explanations

see separate sheet

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EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US 03/33240

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

- 1 Reference is made to the following document:
D1: US 2001/032365 A1 (SRAMEK ROGER) 25 October 2001 (2001-10-25)
- 2 Document D1, which is considered to represent the most relevant state of the art, discloses a mat with an array of individual air filled bladders (§ 31, § 24, § 30) from which the subject-matter of claim 1 differs in that the heat responsive means include a heat sensor and vent structure mounted on an exposed surface of each bladder. The subject-matter of claim 1 is therefore new (Article 33(2) PCT).
 - 2.1 The problem to be solved by the present invention may be regarded as improving comfort and anti-decubitus properties of a mat.
 - 2.2 The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
D1 fails to disclose a mat wherein the heat responsive means include a heat sensor and vent structure mounted on an exposed surface of each air filled bladder. It appears that such a heat sensor and vent structure provides precise adjustment of the pressure in the bladder by making air escape from within the cell (depressurizing it) through the vent that opens only under warming and by allowing air ventilation at the contact surface with the patient, thus contributing to improve comfort and anti-decubitus properties of the mat. In D1, only a modification of parameters such as volume and temperature due to compression and body heat would change the inside pressure of the bladders, but no vent or valve is used because there's no intention to in/outlet air and to ventilate.
 - 2.3 Claims 2-14 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.
 - 2.4 For substantially the same reasons as given for claim 1, independent method claim 17 and its dependent claims 16-23 also meet the requirements of the PCT with

**INTERNATIONAL PRELIMINARY
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respect to novelty and inventive step.

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Numerous decubitus mattress products have been proposed. Many provide only a limited reduction in pressure ulcers or under limited circumstances. Others are too expensive to be affordable and are not readily available. The prior

5 mattresses include lambswool, low-tech foam, high-tech foam, gel-filled mattresses, air mattresses, oscillating air mattresses, and automatic patient tilting mattresses. Diagnostic aids have included the use of pressure sensitive polymer mats to generate a visual readout of the pressure points

10 and pressure distributions. One design of an oscillating pressure mattress uses large tubes arrayed laterally across the mattress. The pressure in these tubes is modulated to oscillate very large body sections. Active or smart decubitus mattresses using high-tech computerized load-sensing devices, numerous

15 sensors, microchips, computer controlled valves, air lines, and other high tech sensing and control components which identify high pressure areas and active re-contour the mat have been proposed. The large number of air bladders with their corresponding large number of electronic components permits a

20 larger range of adjustment of patient contours than passive mattresses such as foams and gels. But, these designs are hardware intensive and are very costly. The high cost has inhibited placing active mattress in mass production so that they become readily available.

25 Despite much research and effort, a need still exists for an improved low-cost decubitus mat.

The present application provides an inexpensive, active decubitus mat which overcomes the above-referenced problems and others.

30

Summary of the Invention

In accordance with one aspect of the present invention, a mat includes an array of individual air-filled bladders and a means responsive to body heat for adjusting air pressure in the individual bladders to adjust contact pressure

35 individually in the bladders. The heat responsive means includes a heat sensor and vent structure mounted on an exposed surface of each bladder.

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F. Harpe

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In accordance with another aspect of the present invention, a method of supporting a subject while reducing the potential for pressure ulcers is provided. The subject is supported on a plurality of air bladders, each of which is
5 pressurized. A temperature at a potential contact point on each bladder is sensed and, responsive to the sensed temperature, the pressure in each bladder is adjusted. The pressure is adjusted in each bladder by venting the bladders, providing an air flow from the bladders along an underside of the subject to reduce
10 pooled moisture.

One advantage of the present invention is that it actively senses and identifies high pressure areas that are highest risk areas for decubitus ulcers.

Another advantage of the present invention is that
15 it automatically adjusts mat contour or pressure at the identified high pressure areas.

Another advantage of the present invention resides in its low cost.

Another advantage of the present invention resides
20 in its simplicity of manufacture.

Still further advantages of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

25 Brief Description of the Drawings

The invention may take form in various components and arrangements of components, and in various steps and
arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed
30 as limiting the invention.

FIGURE 1 is a diagrammatic view of an air mat in accordance with the present invention;

FIGURE 2 is a sectional view through several cells of the mat of FIGURE 1;

35 FIGURE 3 is a top view of one of the vents and associated control of the mat of FIGURES 1 and 2;

FIGURE 4 is a cross-sectional view through the polymer valve control elements of FIGURE 3 in the valve closed position;

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Having thus described the preferred embodiment, the invention is now claimed to be:

1. A mat comprising:
an array of individual, air filled bladders (16);
a means (20) responsive to body heat for adjusting
contact pressure individually in the bladders, the heat
5 responsive means including:
a heat sensor and vent structure (20)
mounted on an exposed surface of each bladder.
2. The mat as set forth in claim 1, wherein the
sensor vent structure (20) includes a confined polymer (28)
which expands under body heat, expansion and contraction of the
polymer controlling a vent valve (26).
3. The apparatus as set forth in claim 2, wherein
the vent valve includes a vent orifice that passes a lower air
flow in a closed state and a higher air flow in an open state.
4. The mat as set forth in claim 2, wherein the
sensor vent structure (20) includes a plurality of flexible,
sealed channels (28), each channel containing the polymer, the
channels deforming as the polymer heats and expands to urge the
5 vent valve (26) open.
5. The mat as set forth in claim 4, wherein as the
polymer expands, the channels create tensile forces that expand
in one dimension and contract in another.
6. The mat as set forth in claim 4, wherein the
channels are curved tubular arrays which generate tensile
stresses (30) in a direction which urges the vent valve (26) to
open.
7. The mat as set forth in claim 2, wherein the
polymer undergoes a phase change between 20-35°C.

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8. The mat as set forth in claim 7, wherein the phase change is a solid/liquid phase change, the polymer having minimal volume change with temperature in the solid state and the liquid state and undergoing significant volume change with the change in phase between the solid and liquid states.

9. The mat as set forth in claim 7, wherein the polymer has as sufficient heat capacity that the polymer changes from the solid phase to the liquid phase at a higher temperature than the polymer changes from the liquid phase back to the solid phase.

10. The mat as set forth in claim 1, further including an air supply (10, 12) which supplies air to the individual bladders (16).

11. The mat as set forth in claim 10, wherein the individual bladders (16), air supply lines (12), and metering orifices (14) between the air supply lines and each bladder are formed of a thin flexible elastomeric material.

12. The mat as set forth in claim 10, further including:

a layer of an air permeable, compressible material which overlays the sensor/vent constructions to help distribute air from the vents around contacting body portions.

13. The mat as set forth in claim 10, further including an overlaying layer of a compressible material whose heat transfer characteristics increase under compression and decrease under expansion.

14. The mat as set forth in claim 1, wherein the mat is incorporated into one of a mattress, a wheelchair seat, an airplane seat, and seating furniture.

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15. A method of supporting a subject while reducing a potential for pressure ulcers, the method comprising:

supporting the subject on a plurality of air bladders

(16);

5

pressurizing each of the air bladders;

sensing a temperature at a potential contact point on each bladder; and,

responsive to the sensed temperature, adjusting a pressure in each bladder, including venting the bladders, the
10 venting providing an air flow from the bladders along an undersigned of the subject to reduce pooled moisture.

16. The method according to claim 15, wherein the sensing step includes:

a polymer expanding as it is heated toward a subject temperature and contracting as it is cooled toward an air
5 temperature in the bladders.

17. The method as set forth in claim 16, wherein the polymer undergoes a phase change between the air supply temperature and the body temperature.

18. The method as set forth in claim 16, wherein the polymer undergoes a phase change between 20-35°C.

19. The method as set forth in claim 16, wherein the venting step includes:

biasing a normally closed vent valve (26) open with the polymer as the polymer expands.

20. The method as set forth in claim 16, wherein the venting step includes:

biasing a vent valve (26) from a state in which it passes a lower air flow to a state in which it passes a higher
5 air flow as the polymer expands.

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21. The method as set forth in claim 19, wherein as the polymer expands and vents the bladder, the bladder collapses and pulls away from the subject;

as the bladder pulls away from the subject, it is
5 cooled by the cooling air and the polymer contracts closing the vent valve (26); and,

as the vent closes, the bladder re-inflates and expands.

22. The method as set forth in claim 21, wherein the polymer has a sufficient heat capacity that the cell over-deflates before the vent valve (26) closes and over-inflates before the vent valve opens to create a massaging
5 action.

23. The method as set forth in claim 21, further including:

overlaying the polymer layer with a material whose heat transfer characteristics improve with compression and
5 diminish with expansion.